

Applicants: Soderlund, Hans E., and Syvanen, Anne-Christine

Filing Date: 26 February 1999

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R E M A R K S

A. Summary of the Claimed Invention

Broadly, the invention of the subject application as amended is directed to a method for detecting the presence of one or more specific nucleotides at a predetermined target position in a target nucleic acid.

The method of the invention includes the step of providing an analyzable amount of the target nucleic acid in a single stranded form. The method further includes the step of hybridizing the target nucleic acid with a detection primer to form a target-nucleic-acid/detection-primer hybrid. The detection primer comprises a detection-primer nucleotide sequence, which has a primer-extension-initiation 3'-end nucleotide that constitutes a 3' end of the detection primer. The detection-primer nucleotide sequence is complementary to a primer-hybridizing nucleotide sequence of the target nucleic acid. A nucleotide in the target nucleic acid complementary to the primer-extension-initiation 3'-end nucleotide of the detection-primer nucleotide sequence defines a primer-end complement nucleotide. The primer-hybridizing nucleotide sequence of the target nucleic acid extends towards the 3' end of the target nucleic acid from the primer-end complement nucleotide. The primer-end complement nucleotide is located in the target nucleic acid at a position 3'-ward of the predetermined target position. The position of the primer-end complement nucleotide is subject to a constraint that no nucleotide of the same type as the one or more specific nucleotides to be detected be located in the target nucleic acid in any position between the position of the primer-end complement nucleotide and the predetermined target position.

The method of the invention for detecting the presence of one or more nucleotides at a target position in a target nucleic acid further includes the step of forming an extension-reaction mixture by exposing the target-nucleic-acid/detection-primer hybrid to an admixture of a polymerization agent and a plurality of nucleoside triphosphates. The nucleoside triphosphates of the admixture include at least one deoxynucleotide and at least one chain-terminating nucleotide analogue. Each deoxynucleotide of the admixture of nucleotides triphosphates is

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complementary to a nucleotide which differs from any nucleotide to which a chain-terminating nucleotide analogue of the admixture is complementary. In a first aspect of the method, at least one deoxynucleotide of the plurality of nucleotide triphosphates of the admixture defines a labeled deoxynucleotide comprising a detectable label or an attachment moiety capable of binding a detectable label. In the first aspect, the plurality of nucleotide triphosphates of the admixture is such that, if a labeled deoxynucleotide is complementary to a specific nucleotide at the predetermined target position, a detectable nucleotide-identifier primer-extension product is formed of the detection primer extended to include an extension portion incorporating the labeled deoxynucleotide. In a second aspect of the method, at least one chain-terminating nucleotide analogue of the plurality of nucleoside triphosphates of the admixture defines a labeled chain-terminating nucleotide analogue comprising a detectable label or an attachment moiety capable of binding a detectable label. In such second aspect, the plurality of nucleotide triphosphates of the admixture is such that, if a labeled chain-terminating nucleotide analogue is complementary to a specific nucleotide at the predetermined target position, a detectable nucleotide-identifier primer-extension product is formed of the detection primer extended to include an extension portion terminated with the labeled chain-terminating nucleotide analogue.

Finally, the method of the invention for detecting the presence of one or more nucleotides at a target position in a target nucleic acid includes the step of analyzing the extension-reaction mixture for the presence or absence of a detectable label in association with, according to the aspect of the method, a labeled deoxynucleotide or a labeled chain-terminating nucleotide analogue incorporated in an extension portion of a primer extension product to detect the presence of the corresponding specific nucleotide at the target position in the target nucleic acid.

B. Summary of the Outstanding Office Action

The attorneys for the applicants note with appreciation that claims 82, 84, 85, 87, 95, 97, and 99 were allowed in the Office Action of 13 January 2005.

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In the outstanding Office Action, claims 83, 86, 88 through 94 inclusive, 96, 98, 100, and 101 were finally rejected under 35 USC §112, first paragraph, with the assertion that the claims contained subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

**C. Summary of the Present Amendments
and Request for Reconsideration**

Although the attorneys for the applicants maintain their position that claims 83, 86, 88 through 94 inclusive, 96, 98, 100, and 101 of the subject application fully meet the standards of 35 USC §112, first paragraph for the reasons set forth in a previous reply dated 21 October 2004, in order to expedite prosecution of the subject application, rejected independent claims 83 and 86 have been cancelled without prejudice in the present reply after final action. Furthermore, dependent claims 84 and 87 have been cancelled without prejudice and dependent claims 88 through 90 inclusive and 93 through 101 inclusive have been amended to eliminate dependencies on rejected independent claims 83 and 86. The applicants expressly reserve the right to prosecute claims directed to the subject matter of any of cancelled claims 83, 84, 86, and 87 and claims dependent thereon in one or more continuation, divisional, or other continuing patent application.

Reconsideration of the subject application as amended above is respectfully requested.

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D. Conclusion

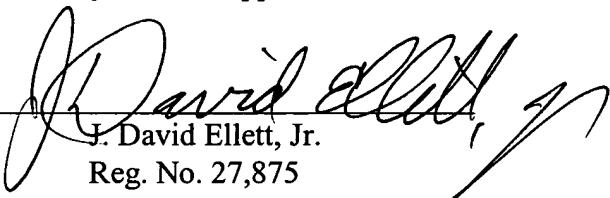
As noted above, independent claims 82 and 85 were allowed over the art of record in the Office Action of 13 January 2005. It is submitted that dependent claims 88 through 101 inclusive of the application as amended herein are likewise allowable over the art of record. Withdrawal of the final rejection and early allowance of the application are therefore earnestly solicited.

Respectfully submitted,

Attorneys for the Applicants

by

J. David Ellett, Jr.
Reg. No. 27,875

A handwritten signature in black ink, appearing to read "J. David Ellett, Jr.", is written over a horizontal line. The signature is fluid and cursive.

Telephone No.: (212) 813-1600